DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

412

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-83

September 8, 1997

Mr. Ricardo A. Balda
President, CEO
MediComp, Inc.
7845 Ellis Road
Melbourne, FL 32904

Dear Mr. Balda:

We are writing to you because on August 14, 15 & 25, 1997 FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving ECG monitors and recorders which are manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the CGMP. These violations include, but are not limited to the following:

- Failure to establish and implement an adequate complaint handling program, e.g., some investigations such as RMAs 501-1, 589 and 906 are not recorded; some available investigation records such as RMAs H2751, DC00195 and KB00293 are not complete; not all complaints are trended to ascertain failure modes; and not all complaint records describe the cause of the failure or the correction made when the conclusion was recorded as a "Return & Repair."

- Failure to document, review, approve, implement and validate changes to components, finished devices,

labeling, packaging or manufacturing process specifications, e.g., change control records used for documentation and approval of changes, such as ECN 629 and Discrepant Material Report 3963 used for change control documentation, do not include the problem or reason for the change to allow for adequate review; the DMR 3963 used to change vendors in order to correct the failure mode involving the LEDs does not contain quality requirements needed for the proposed suppliers to allow for adequate review, and there is no record of the verification or validation of the above two corrective actions that would ensure the actions taken were effective and would not adversely affect the finished product.

- Failure to establish and document adequate procedures for changes to a specification, method, process, or procedure, e.g., available procedures do not stipulate who or what positions are required for approval and the mechanism for assigning an effective date.

- Failure to verify significant manufacturing processes and quality assurance tests, e.g., there are no finished written QA procedures for the operational profiles of the reflow oven; there are no written acceptance specifications for the reflow profiles; there are no records of the reflow oven QA testing, and replacement thermocouples for the reflow oven are not tested before use.

- Failure to establish new procedures required by the Quality Systems Regulations, including but not limited to training, purchasing controls and servicing.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the GMPs and does not necessarily address other obligations you have under the law. You may obtain general information about all the FDA requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-/800/638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the GMP requirements and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,

Douglas D. Tolen
Director
Florida District

Enclosure